DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 2, 2014

POLYMER TECHNOLOGY SYSTEMS, INC.
JACK ROGERS
DIRECTOR, REGULATORY AFFAIRS
7736 ZIONSVILLE ROAD
INDIANAPOLIS IN 46268

Re: K142302
Trade/Device Name: BioScanner Plus Glucose Test System
PTS PANELS Chol+Glu Test Panel System
PTS PANELS Lipid Panel Test System
PTS PANELS HDL Cholesterol Test System
PTS PANELS CHOL+HDL Panel Test System
PTS PANELS CHOL+HDL+GLU Panel Test System
PTS PANELS Metabolic Chemistry Panel Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CGA, CHH, JGY, LBR, MRR
Dated: August 15, 2014
Received: August 18, 2014

Dear Mr. Jack Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K142302

Device Name
BioScanner Plus Glucose Test System, PTS PANELS Chol+Glu Test Panel System, PTS PANELS Lipid Panel Test System, PTS PANELS HDL Cholesterol Test System, PTS PANELS CHOL+HDL Panel Test System, PTS PANELS CHOL+HDL+GLU Panel Test System, PTS PANELS Metabolic Chemistry Panel Test System

Indications for Use *(Describe)*

The BioScanner Plus Glucose Test Systems are intended for the quantitative determination of glucose in human whole blood for use by healthcare professionals in both physicians' office and in acute and convalescent care facility bedside testing. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia and of pancreatic islet cell carcinoma.

The Chol+Glu Test Panel system is intended to measure cholesterol and glucose in whole blood on a BioScanner Plus (CardioChek brand) analyzer. The test strips are intended to be used by healthcare professionals to measure blood cholesterol and glucose. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Glucose measurements are used in the management of carbohydrate metabolism disorders.

The Lipid Panel Test system is intended to measure cholesterol, HDL cholesterol and triglycerides in whole blood on a BioScanner Plus (CardioChek brand) analyzer. The test strips are intended to be used by healthcare professionals to measure three blood analytes: cholesterol, HDL cholesterol and triglycerides. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.

The PTS PANELS HDL Cholesterol Test system is intended to measure high density lipoprotein cholesterol in whole blood. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

The PTS PANELS CHOL+HDL Panel Test system is intended to be used by medical professionals to measure cholesterol and high density lipoprotein cholesterol in whole blood. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various liver and renal diseases.

The PTS PANELS CHOL+HDL+GLU Panel Test system is intended to be used by medical professionals to measure cholesterol, high density lipoprotein cholesterol and glucose in whole blood. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Glucose measurements are used by individuals with diabetes to measure glucose in fingerstick whole blood at home for the management of carbohydrate metabolism disorders.

The PTS PANELS Metabolic Chemistry Panel Test system is intended to be used by medical professionals to measure glucose, high density lipoprotein cholesterol and triglycerides in fingerstick whole blood. Glucose measurements are used in the management of carbohydrate metabolism disorders. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**510(k) Summary**

**1. Applicant Information:**

Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

**Contact Person:** Jack Rogers
**Phone:** 317-870-5610
**Fax:** 317-870-5608

**2. Date of Preparation:**

September 26, 2014

**3. Trade Name:**

BioScanner Plus Glucose Test System
PTS PANELS Chol+Glu Test Panel System
PTS PANELS Lipid Panel Test System
PTS PANELS HDL Cholesterol Test System
PTS PANELS CHOL+HDL Panel Test System
PTS PANELS CHOL+HDL+GLU Panel Test System
PTS PANELS Metabolic Chemistry Panel Test System

**4. Device Description:**

The above named test systems are for in vitro diagnostic use with the prescription use BioScanner Plus (CardioChek PA) reflectance photometer.

The above named test systems are modified in this submission by the addition of a CardioChek ChekMate strip for use only with the prescription use analyzer. CardioChek ChekMate strips are dry strips that mimic the use of the PTS PANELS test strips to check the CardioChek analyzer system optics, calibration and result handling algorithms. ChekMate strips should not be used as a substitute for liquid quality control materials. There is no change to any of the test strips in any of the above named systems.

**5. Classification Names:**

Glucose Test System
Panel: Clinical Chemistry 75
Product Codes: CGA
Device Classification: Class 2 (Regulation 21CFR 862.1345)

Cholesterol Test System
Panel: Clinical Chemistry 75
Product Codes: CHH
Device Classification: Class I (Regulation: 21 CFR 862.1175*)
* Meets limitations of exemption as per 21 CFR 862.9 (c)(4)

Triglyceride Test System
Panel: Clinical Chemistry 75
Product Codes: JGY
Device Classification: Class I (Regulation: 21 CFR 862.1705*)
* Meets limitations of exemption as per 21 CFR 862.9 (c)(4)

Lipoprotein Test System
Panel: Clinical Chemistry 75
Product Codes: LBR, MRR
Device Classification: Class I (Regulation: 21 CFR 862.1475*)
* Meets limitations of exemption as per 21 CFR 862.9 (c)(4)

**6. Intended Use**

The BioScanner Plus Glucose Test Systems are intended for the quantitative determination of glucose in human whole blood for use by healthcare professionals in both physicians' office and in acute and convalescent care facility bedside testing. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia and of pancreatic islet cell carcinoma.

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The Lipid Panel Test system is intended to measure cholesterol, HDL cholesterol and triglycerides in whole blood on a BioScanner Plus (CardioChek brand) analyzer. The test strips are intended to be used by healthcare professionals to measure three blood analytes: cholesterol, HDL cholesterol and triglycerides. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.

The PTS PANELS HDL Cholesterol Test system is intended to measure high density lipoprotein cholesterol in whole blood. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

The PTS PANELS CHOL+HDL Panel Test system is intended to be used by medical professionals to measure cholesterol and high density lipoprotein cholesterol in whole blood. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various liver and renal diseases.

The PTS PANELS CHOL+HDL+GLU Panel Test system is intended to be used by medical professionals to measure cholesterol, high density lipoprotein cholesterol and glucose in whole blood. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Glucose measurements are used by individuals with diabetes to measure glucose in fingerstick whole blood at home for the management of carbohydrate metabolism disorders.

The PTS PANELS Metabolic Chemistry Panel Test system is intended to be used by medical professionals to measure glucose, high density lipoprotein cholesterol and triglycerides in fingerstick whole blood. Glucose measurements are used in the management of carbohydrate metabolism disorders. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.

**7. Reason for 510(k):**

Device Modification

**8. Predicate Device Information**

| | |
|---|---|
| Device Trade Name: | PTS PANELS CHOL+HDL+GLU Panel Test Strips<br>PTS PANELS Metabolic Chemistry Panel Test Strips |
| Device Company: | Polymer Technology Systems, Inc. |
| 510(k) number: | k071507 and k070017 |

Comparison to Predicate:

Each system is identical to the unmodified system with the exception of the addition of the ChekMate strip.

**9. Performance Characteristics**

The strips for each system are identical to the previously cleared strips. The prescription use BioScanner Plus (CardioChek PA) analyzer is unmodified compared to the predicate device with the exception of the addition of the CardioChek ChekMate strips.

**CardioChek ChekMate Strips Value Assignment:**

Following assembly of a lot of ChekMate strips (up to 400 pieces per lot), 45 strips are evaluated on a single CardioChek PA meter. The four results (% R) for each analyzer (C1 RED, C2 RED, C3 RED, C1 GREEN) are recorded and the average, minimum and maximum results are determined and evaluated for meeting acceptable ranges.

The acceptable value ranges to be printed on the ChekMate range card are calculated as the minimum result minus 1% R (MIN) to the maximum result plus 1% R (MAX). This range (MAX – MIN) is then evaluated for appropriateness and acceptability. The range is acceptable if it is at least 5% R, but not more than 10% R. Every ChekMate strip is then measured on a different CardioChek PA meter to verify that every strip will pass these ranges.

Each package of ChekMate strips contains a range card which lists the lot specific expected ranges for each of the four measurements for Level 1 and Level 2.

**CardioChek ChekMate Strips Stability:**

Real-time Stability:

A real-time stability study was performed on four (4) lots of ChekMate Strips. Prior to study initiation, each lot was tested 30 times to establish the baseline result (Result $_{baseline}$). The strips were tested at predetermined intervals throughout the one hundred and four week study. The percent recovery ((Result ÷ Result $_{baseline}$) * 100) was calculated. Percent recovery was required to be 100±20% to consider the test as passed. All four lots at each of the two levels passed the criterion.

The study supports an 18 month stability claim.

Re-use Stability:

The stability of ChekMate for repeated re-use was verified over a 9 month study using 13 CardioChek PA analyzers. Individual ChekMate strips were tested for 1,253 uses.

Each result was evaluated against the acceptable performance range published for the lot. If a test result did not meet this range, the test was to be repeated. The acceptance criteria for the re-use stability study was lower than 2% failures on the first test and no failures upon re-test. The acceptance criteria was met for 1,253 uses and the claimed re-use stability is 500 uses for the ChekMate strips.

**10. Conclusion:**

The performance characteristics above demonstrate that the modification of the above named test systems by the addition of the CardioChek ChekMate strips are substantially equivalent to the unmodified systems.